

**REMARKS**

Claims 1- 54 were pending in the application. Claims 2, 3, 6, 7, and 18-54 have been canceled. Claims 1 and 13-15 have been amended and new claims 55-68 have been added. Accordingly, upon entry of the amendment presented herein claims 1, 4, 5, 8-17, and 55-67 will be pending in the application.

Support for the amendments to the specification and to the claims may be found throughout the specification and claims as originally filed. *No new matter has been added.*

Support for the amendments to claim 1 and new claim 55 may be found at, for example, page 45, line 28, through page 46, line 2 of the substitute specification; support for the amendments to claim 13 may be found at, for example, page 28, lines 20-25 and page 5, lines 17-18 of the substitute specification; support for new claims 56 and 57 may be found at, for example, page 10, lines 20-27 of the substitute specification; support for new claim 58 may be found at, for example, page 6, lines 13-15 of the substitute specification; support for new claims 59, 63, and 64 may be found at, for example, page 30, lines 6-10, page 74, lines 3-8, and page 78, lines 1-18 of the substitute specification; support for new claim 60 may be found at, for example, page 37, lines 24-28 of the substitute specification; support for new claims 61 and 62 may be found at, for example, page 75, lines 1-10 and page 76, lines 9-10 of the substitute specification; support for new claim 65 may be found at, for example, page 30, lines 22-26 of the substitute specification; and support for new claims 66 and 67 may be found at, for example, page 27, lines 14-22 and page 53, lines 10-17 of the specification.

Any amendments to and/or cancellation of the claims are not to be construed as an acquiescence to any of the rejections set forth in the instant Office Action, and were done solely to expedite prosecution of the application. Applicants hereby reserve the right to pursue the subject matter of the claims as originally filed in this or a separate application(s).

**Election/Restriction**

The Examiner has required restriction to one of the following inventions under 35 U.S.C. §121:

Group I. Claims 2-5 and 11-17, drawn to a method for identifying a compound which modulates an interaction between a first and a second polypeptide, the method comprising contacting in vitro a non-transgenic cell having a first polypeptide comprising a binding portion

of a KRC polypeptide and a second polypeptide comprising a binding portion of a polypeptide selected from the group consisting of GATA3, SMAD or Runx2, classified in class 435, subclass 4.

Group II . Claims 2-17, drawn to a method for identifying a compound which modulates an interaction between a first and a second polypeptide, the method comprising contacting in vitro a transgenic cell having a first polypeptide comprising a binding portion of a KRC polypeptide and a second polypeptide comprising a binding portion of a polypeptide selected from the group consisting of GATA3, SMAD or Runx2;

Group III. Claims 2-5 and 11-17, drawn to a method for identifying a compound which modulates an interaction between a first and a second polypeptide, the method comprising contacting in vivo a non-transgenic cell having a first polypeptide comprising a binding portion of a KRC polypeptide and a second polypeptide comprising a binding portion of a polypeptide selected from the group consisting of GATA3, SMAD or Runx2;

Group IV. Claims 2-7 and 11-17, drawn to a method for identifying a compound which modulates an interaction between a first and a second polypeptide, the method comprising contacting in vivo a transgenic cell having a first polypeptide comprising a binding portion of a KRC polypeptide and a second polypeptide comprising a binding portion of a polypeptide selected from the group consisting of GATA3, SMAD or Runx2;

Group V. Claim 19, drawn to a method of identifying compounds which modulate a biological activity of mammalian KRC, the method comprising contacting in vitro cells deficient in KRC or a molecule in a signaling pathway involving KRC with a test compound;

Group VI. Claims 19-20, drawn to a method of identifying compounds which modulate a biological activity of mammalian KRC, the method comprising contacting in vivo cells deficient in KRC or a molecule in a signaling pathway involving KRC with a test compound;

Group VII. Claim 22, drawn to an in vitro method of identifying compounds which modulate a biological activity of mammalian KRC, wherein the indicator composition is a non-transgenic cell that expresses KRC and at least one molecule selected from the group consisting of GATA3, SMAD and Runx2;

Group VIII. Claim 22, drawn to an in vitro method of identifying compounds which modulate a biological activity of mammalian KRC, wherein the indicator composition is a transgenic cell that expresses KRC and at least one molecule selected from the group consisting of GATA3, SMAD and Runx2;

Group IX. Claim 22, drawn to an in vivo method of identifying compounds which modulate a biological activity of mammalian KRC, wherein the indicator composition is a non-transgenic cell that expresses KRC and at least one molecule selected from the group consisting of GATA3, SMAD and Runx2,;

Group X. Claim 22, drawn to an in vivo method of identifying compounds which modulate a biological activity of mammalian KRC, wherein the indicator composition is a

transgenic cell that expresses KRC and at least one molecule selected from the group consisting of GATA3, SMAD and Runx2;

Group XI. Claim 23, drawn to an in vitro, cell-free method of identifying compounds which modulate a biological activity of mammalian KRC;

Group XII. Claims 47-48, drawn to a transgenic non-human animal in which a KRC transgene is mis-expressed; and

Group XIII. Claims 49-54, drawn to a transgenic non-human animal in which the gene encoding KRC is disrupted.

The Examiner has also required the following species elections:

If any one of Groups I-IV and VII are elected, we are required to elect a single disclosed host cell type.

If any one of Groups V-XI are elected, we are required to elect a single disclosed of KRC or a molecule in a signal transduction pathway involving KRC.

If any one of Groups VI, VII-X, XII-XIII are elected, we are required to elect a single disclosed species of non-human animal.

Furthermore, the Examiner has required the following additional species elections:

A single disclosed species of determination method steps from the lists recited in Claims 9-11 and 13-15 in accordance with the elected Group;

A single disclosed second polypeptide indicator species, *i.e.*, GATA3, SMAD2, SMAD3, or Runx2; and

A single disclosed biological activity species that is to be measured from the list recited in Claims 13, 19 and 21.

As an initial matter, Applicants note that the instant Restriction Requirement fails to mention claims 24-45. Although Applicants have canceled claims 24-45 herein, Applicants respectfully request that the Examiner clarify this omission for the record.

With respect to the Restriction Requirement set forth in the instant Office Action, Applicants' respectfully traverse the foregoing Restriction Requirement and submit that the requirement is improper. However, in order to be considered responsive to the instant Office Action, Applicants' hereby elect Group I, Claims 2-5 and 11-17, drawn to a method for

identifying a compound which modulates an interaction between a first and a second polypeptide, the method comprising contacting *in vitro* a non-transgenic cell having a first polypeptide comprising a binding portion of a KRC polypeptide and a second polypeptide comprising a binding portion of a polypeptide selected from the group consisting of GATA3, SMAD or Runx2, *with traverse*.

Applicants traverse the restriction requirement to the extent that Groups I-IV should be reformed as a single group containing claims 1-17 (referred to hereinafter as "*newly formed Group I*") for the reasons set forth below.

Applicants note that all of the claims, as amended, are directed to *in vitro* methods, however prior to the instant amendment Applicants submit that claim 1 was an allowable generic claim and that Groups I-IV have the same mode of operation, function and effect, *e.g.*, structural components. Specifically, the starting materials of each group are the same, *e.g.*, a KRC polypeptide and a polypeptide selected from the group consisting of GATA3, SMAD or Runx2.

In addition, as Groups I-IV are of the same class, a literature search of all Groups I-IV would be nearly, if not completely, co-extensive. Accordingly, Applicants respectfully submit that a sufficient search and examination with respect to the claimed methods can be made without serious burden on the Examiner. As the M.P.E.P. states:

[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions. M.P.E.P. § 803.

Applicants thus respectfully submit that the search with regard to the method for identifying a compound which modulates an interaction between a first and a second polypeptide comprising contacting *in vitro* a non-transgenic cell (Group I) would be coextensive with a search with regard to method for identifying a compound which modulates an interaction between a first and a second polypeptide comprising contacting *in vitro* a transgenic cell (Group II) would be coextensive with a search with regard to method for identifying a compound which modulates an interaction between a first and a second polypeptide comprising contacting *in vivo* a non-transgenic cell (Group III) would be coextensive with a search with regard to method for identifying a compound which modulates an interaction between a first and a second polypeptide comprising contacting *in vivo* a transgenic cell (Group IV), and would not place a burden on the Examiner.

It is Applicants' position that the restriction under 35 U.S.C. §121 is improper. In view of the above traversal, Applicants hereby elect ***newly formed Group I***, claims 1-17, drawn to method for identifying a compound which modulates an interaction between a first and a second polypeptide, the method comprising contacting *a cell* having a first polypeptide comprising a binding portion of a KRC polypeptide and a second polypeptide comprising a binding portion of a polypeptide selected from the group consisting of GATA3, SMAD or Runx2.

Accordingly, it is respectfully requested that the restriction requirement be withdrawn, and that all of the claims presently pending in this application be examined.

With respect to the species elections required by the Examiner, Applicants elect, without traverse, the following species:

A mouse T cell as the host cell type;

Co-immunoprecipitation (claim 11) as the method of determination;

GATA3 as the second polypeptide; and

Th2 cell differentiation as the biological activity.

Claims 1, 4, 5, 11-17, 55-66 read on the species of a mouse T cell. Claims 1, 4, 5, 11, 13, 16, 17, 55-58, 60-62, 66, and 67 read on the species of co-immunoprecipitation. Claims 1, 8-17, 55-67 read on the species GATA3 as the second polypeptide. Claims 1, 4, 5-17, 55-67 read on the species of Th2 cell differentiation as the biological activity.

Applicants reserve the right to traverse the above restriction with respect to non-elected Groups II-XIII in this or subsequent applications.

**SUMMARY**

If a telephone conversation with Applicants' Attorney would expedite the prosecution of the above-identified application, the Examiner is urged to call Applicants' Attorney at (617) 227-7400.

Applicant believes no fee is due with this statement. However, if a fee is due, please charge our Deposit Account No. 12-0080, under Order No. HUI-045CP2US from which the undersigned is authorized to draw.

Dated: July 23, 2009

Respectfully submitted,

Electronic Signature: /Andrew T. Wilkins/  
Andrew T. Wilkins, Ph.D.  
Registration No. 64,753  
LAHIVE & COCKFIELD, LLP  
One Post Office Square  
Boston, Massachusetts 02109-2127  
(617) 227-7400 (Tel.)  
(617) 742-4214 (Fax)  
Attorney for Applicants